

Docket No.: 337924US59SD

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF: : EXAMINER: ROBINSON, B.
TOSHIHARU OHTA, ET AL : GROUP ART UNIT: 1625
SERIAL NO.: 10/773,344 : U.S. PATENT NO.: 7,342,014
FILED: FEBRUARY 9, 2004 : ISSUED: MARCH 11, 2008
FOR: DIAMINE DERIVATIVES

PETITION UNDER 37 C.F.R. §1.183

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

SIR:

Petitioners hereby request that the Director suspend the rules and consider their Petition Under 37 C.F.R. §1.705(d) and Request for Reconsideration of Patent Term Adjustment **submitted herewith.**

When the patent term adjustment finally calculated by the Office is incorrect, patentees have two mechanisms by which to challenge the patent term adjustment. These two mechanisms are:

- 1) 37 CFR §1.705(d) - (e) relate to Requests for Reconsideration of the USPTO-determined patent term adjustment. 37 CFR §1.705(d) - (e) are reproduced below (*with emphasis added*):

(d) If there is a revision to the patent term adjustment indicated in the notice of allowance, the patent will indicate the revised patent term adjustment. If the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed ***within two months of the date the patent issued*** and must comply with the requirements of paragraphs (b)(1)

and (b)(2) of this section. Any request for reconsideration under this section that raises issues that were raised, or could have been raised, in an application for patent term adjustment under paragraph (b) of this section shall be dismissed as untimely as to those issues.

(e) The periods set forth in this section are ***not extendable***.

- 2) 35 U.S.C. §154(b)(4)(A) permits a challenge the USPTO calculated patent term adjustment by a civil action against the Director at the District Court for the District of Columbia within 180 days of patent grant.

The above-identified application published as U.S. 7,342,014 on March 11, 2008. On September 30, 2008, the District Court for the District of Columbia issued a decision related to the calculation of patent term adjustment - In *Wyeth v. Dudas*, Civil Action No. 07-1492 (JR) (2008 U.S. Dist. Lexis 76063 (D.D.C., September 30, 2008), copy **enclosed herewith**. In *Wyeth*, the Court issued an opinion explaining the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b). Specifically, when determining the overlap defined in 35 U.S.C. §154(b)(2), the *Wyeth* Court held that “[t]he only way that [A and B] periods of time can 'overlap' is if they occur on the same day” (see page 3, left column, first fully paragraph). In other words, the A delay (i.e., delay under 35 U.S.C. §154(b)(1)(A)) and B delay (i.e., delay under 35 U.S.C. §154(b)(1)(B)) only overlap if the A delay occurs after three years of pendency.

The *Wyeth* decision has direct relevance to the above-identified patent as the Office has improperly calculated the patent term adjustment for the above-identified patent. As set forth in the Petition Under 37 C.F.R. §1.705(d) and Request for Reconsideration of Patent Term Adjustment, submitted herewith, under *Wyeth* the above-identified patent should be entitled to an additional **396 days** of patent term adjustment resulting in a total patent term adjustment of **753** days.

37 C.F.R. §1.183 provides:

In an extraordinary situation, when justice requires, *any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived* by the Director or the Director's designee, *sua sponte*, or on petition of the interested party, subject to such other requirements as may be imposed.

Although *Wyeth* is controlling of the issue in this case and, as such, is directly applicable to the case at hand, the applicability of this decision to the above-identified patent was not appreciated by Petitioners until after the passage of 180-days from patent issuance. Accordingly, there is no possible rule or statutory relief specifically available to Petitioners despite the Office's error in calculating the patent term adjustment for the present application. Thus, this case represents an extraordinary situation where justice requires remedial action.

Petitioners submit that whereas the 180-day limit to file a civil action against the Director at the District Court for the District of Columbia is statutory, the 2-month non-extendible period for filing a Request for Reconsideration does not appear in the statute, but rather is only presented in the regulations. Thus, the Office is requested, and justice requires, to waive the 2-month non-extendible limit appearing in the regulations and permit Petitioners the opportunity to have their Petition Under 37 C.F.R. §1.705(d) and Request for Reconsideration of Patent Term Adjustment properly decided.

In accordance with the provisions of 37 C.F.R. §1.183, Petitioners submit herewith the requisite fee under 37 C.F.R. §1.17(f). In the event that the Office determines that additional fees are required, it is requested that any underpayment be charged to their undersigned Representative's deposit account (Deposit Account No. 15-0030).

For the foregoing reasons, Petitioners respectfully submit that the Request for Suspension of the Rules should be GRANTED and the Petition Under 37 C.F.R. §1.705(d) and Request for Reconsideration of Patent Term Adjustment submitted herewith should be entered and favorably reviewed. Early notification of such action is earnestly solicited.

Respectfully submitted,

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WYETH v. Dudas
Civil Action No. 07-1492 (JR)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2008 U.S. Dist. LEXIS 76063 (D.D.C., September 30, 2008)

OPINION BY: JAMES ROBERTSON

MEMORANDUM OPINION

Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. Section 154(a)(2) establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b)(1)(A), and, regardless of the reason, whenever the patent prosecution takes more than three years, 35 U.S.C. § 154(b)(1)(B). Recognizing that the protection provided by these separate guarantees might overlap, Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

Statutory Scheme

Until 1994, patent terms were 17 years from the date of issuance. *See* 35 U.S.C. § 154 (1992) ("Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States. . ."). In 1994, in order to comply with treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. *See* Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which -- referred to as the Patent Term Guarantee Act of 1999 -- provided for the adjust-

ments that are at issue in this case. Pub. L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in subsection (b)(1)(A), the "[g]uarantee of prompt Patent and Trademark Office response." It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. *See* 35 U.S.C. § 154(b)(1)(A)(i)-(iv). Periods of delay that fit under this provision are called "A delays" or "A periods." The second provision is the "[g]uarantee of no more than 3-year application pendency." Under this provision, a one-day term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO. ¹ *See* 35 U.S.C. § 154(b)(1)(B). The period that begins after the three-year window has closed is referred to as the "B delay" or the "B period." ("C delays," delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

¹ Certain reasons for exceeding the three-year pendency period are excluded, *see* 35 U.S.C. § 154(b)(1)(B)(i)-(iii), as are periods attributable to the applicant's own delay. *See* 35 U.S.C. § 154(b)(2)(C).

The extensions granted for A, B, and C delays are subject to the following limitation:

(A) In general.--To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). This provision is manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer the question of what is double-counting and what is not. Proper

interpretation of this proscription against windfall extensions requires an assessment of what it means for "periods of delay" to "overlap."

The PTO, pursuant to its power under 35 U.S.C. § 154(b)(3)(A) to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," has issued final rules and an "explanation" of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, *see* 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A), which was published on June 21, 2004, at 69 Fed. Reg. 34238. Here, the PTO "explained" that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), *the entire period during which the application was pending before the Office* (except for periods excluded under 35 U.S.C. § 154 (b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, *is the relevant period under 35 U.S.C. § 154 (b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).*

69 Fed. Reg. 34238 (2004) (emphasis added). In short, the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for "A delay" or for "B delay," whichever is larger, but never A + B.

In the plaintiffs' submission, this interpretation does not square with the language of the statute. They argue that the "A period" and "B period" overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are two "A periods," each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is 1/1/07, but the patent does not issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the "B period" begins running on 1/1/05, three years after the patent application was filed, and ends

three years later, with the issuance of the patent on 1/1/08. In this example, then, the first "A period" does not overlap the "B period," because it occurs in 2003-04, not in 2005-07. The second "A period," which covers 365 of the same days covered by the "B period," does overlap. Thus, in plaintiff's submission, this patent holder is entitled to four years of adjustment (one year of "A period" delay + three years of "B period" delay). But in the PTO's view, since "the entire period during which the application was pending before the office" is considered to be "B period" for purposes of identifying "overlap," the patent holder gets only three years of adjustment.

Chevron Deference

We must first decide whether the PTO's interpretation is entitled to deference under *Chevron v. NRDC*, 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984). No, the plaintiffs argue, because, under the Supreme Court's holdings in *Gonzales v. Oregon*, 546 U.S. 243, 126 S. Ct. 904, 163 L. Ed. 2d 748 (2006), and *United States v. Mead Corp.*, 533 U.S. 218, 121 S. Ct. 2164, 150 L. Ed. 2d 292 (2001), Congress has not "delegated authority to the agency generally to make rules carrying the force of law," and in any case the interpretation at issue here was not promulgated pursuant to any such authority. *See Gonzales*, 546 U.S. at 255-56, *citing Mead*, 533 U.S. at 226-27. Since at least 1996, the Federal Circuit has held that the PTO is not afforded *Chevron* deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. *See Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).

Here, as in *Merck*, the authority of the PTO is limited to prescribing "regulations establishing procedures for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO's authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to "prescribe regulations establishing the *circumstances that constitute* a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added) — that is, the power to elaborate on the meaning of a particular statutory term. No such power is granted under § 154(b)(3)(A). *Chevron* deference does not apply to the interpretation at issue here.

Statutory Construction

Chevron would not save the PTO's interpretation, however, because it cannot be reconciled with the plain

text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at *Chevron's* "step one," without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., *MCI v. AT&T*, 512 U.S. 218, 229, 114 S. Ct. 2223, 129 L. Ed. 2d 182 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether "periods of delay attributable to grounds specified in paragraph (1) overlap." The only way that periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its interpretation as essentially running the "period of delay" under subsection (B) from the filing date of the patent application, such that a period of "B delay" *always overlaps* with any periods of "A delay" for the purposes of applying § 154(b)(2)(A).

The problem with the PTO's construction is that it considers the application *delayed* under § 154(b)(1)(B) during the period *before it has been delayed*. That construction cannot be squared with the language of § 154(b)(1)(B), which applies "if the issue of an original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added.) "B delay" begins when the PTO has failed to issue a patent within three years, not before.

The PTO's interpretation appears to be driven by Congress's admonition that any term extension "not ex-

ceed the actual number of days the issuance of the patent was delayed," and by the PTO's view that "A delays" during the first three years of an applications' pendency inevitably lead to "B delays" in later years. Thus, as the PTO sees it, if plaintiffs' construction is adopted, one cause of delay will be counted twice: once because the PTO has failed to meet an administrative deadline, and again because that failure has pushed back the entire processing of the application into the "B period." Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that -- again from the PTO's viewpoint -- the applicant is not "compensated" for the PTO's administrative delay, he is benefited by it.

But if subsection (B) had been intended to guarantee a 17-year patent term and *no more*, it could easily have been written that way. It is true that the legislative context -- as distinct from the legislative history -- suggests that Congress may have intended to use subsection (B) to guarantee the 17-year term provided before GATT. But it chose to write a "[g]uarantee of no more than 3-year application pendency," 35 U.S.C. § 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in subsection (A). The PTO's efforts to prevent windfall extensions may be reasonable -- they may even be consistent with Congress's intent -- but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

JAMES ROBERTSON

United States District Judge